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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,022

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Gopal K. Chopra

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EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,022	Applicant(s) CHOPRA, GOPAL K.	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-13 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-13 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

1. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive. Applicant contends that the previous rejection was improper because the cited Sliwa (US Patent No. 5,560,362) lacks a "transducer secured to a catheter" and a catheter comprising "a channel located adjacent the transducer adapted for carrying cooling fluid" (Remarks p. 6 paragraph 1). Applicant goes on to argue that Sliwa ('362) lacks a catheter comprising "a distal end, a proximal end, and a lumen extending therebetween and means for cooling the catheter distal end," nor does the reference teach a step of "introducing a catheter carrying a transducer into a body" (Remarks p. 6 paragraph 2).

Regarding the "transducer secured to a catheter," and the "channel...adapted for carrying cooling fluid," Examiner maintains that the reference disclosure of using the transducer with multi-element catheter-based imaging transducers (col. 22 lines 2-3) inherently requires that the transducer be "secured" to the catheter. It is known in the art that catheter-based transducers essentially comprise an imaging transducer delivered within a standard, state of the art catheter. As evidentiary support, Examiner relies on the disclosure of Griffith (US Patent No. 5,109,861), which shows an exemplary state of the art catheter having a lumen which accepts an ultrasound transducer. Therefore, according to what is known and used in the art of catheter-based ultrasound imaging, Sliwa ('362) does in fact anticipate a transducer secured to a catheter. Furthermore, Sliwa ('362) discloses a tube that can be positioned external to and along the length of the transducer (col. 9 lines 55-58, col. 10 lines 17-24, col. 11 lines 33-45), wherein the tube is adapted for carrying a cooling substance; this tube can be reasonably considered to constitute a "channel located adjacent the transducer" as claimed.

Regarding Applicant's argument that Sliwa ('362) fails to teach or suggest a catheter having distal and proximal ends and a lumen therebetween, Examiner maintains that these features are inherent to any state of the art catheter. Examiner respectfully directs Applicant's attention to the definition of the word "catheter" as set forth by Merriam Webster:

catheter: *a tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open*

A tube inherently has proximal and distal ends, as well as a lumen as claimed. Furthermore, the terms "proximal" and "distal" could be construed as a claim of intended use or functional language, as

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that which is proximal or distal to the operator is determined by the manner in which the catheter is disposed relative to the operator.

Regarding Applicant's argument that the cited references fail to teach or suggest a step for "introducing a catheter into a body," Examiner again directs Applicant's attention to the definition of the word catheter, which describes its standard use requiring insertion into canals, vessels, passageways or body cavities. Therefore, by disclosing use of the reference invention in conjunction with state of the art imaging catheters, Sliwa ('562) inherently discloses that the catheter is introduced into a body as claimed.

As Applicant's arguments are wholly unpersuasive to overcome the prior art of record, the previous rejections of claims 1-4, 8-13 and 21-24 under 35 U.S.C. 102 and 103 are maintained and reiterated herein.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 9-13 and 21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sliwa et al (US Patent No. 5,560,362), hereinafter Sliwa ('362), previously made of record.

Sliwa ('362) discloses an apparatus and method for delivering acoustic energy to a target site comprising a catheter (col. 21 line 64 – col. 22 line 3), wherein the apparatus includes a transducer having a surface configured to be placed on a tissue (Fig. 1), a channel adjacent to the transducer and adapted for carrying cooling fluid, a fluid source, a lumen in communication with the channel and fluid source (col. 13 lines 21-66), a heat exchanger (col. 13 lines 47-49), and an acoustic energy sensor adjacent the transducer, wherein the acoustic energy sensor comprises a neurological signal sensor. Sliwa ('362) additionally discloses steps for sensing a reflected acoustic signal associated with the delivered acoustic energy, and analyzing the reflected acoustic signal to determine a location of a vessel ("catheter-based imaging or doppler transducers," col. 21 line 64 – col. 22 line 3).

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sliwa ('362). Sliwa ('362) substantially teaches all features of the present invention as previously discussed for claim 21, with the exception of the step of delivering a blood thinning agent to the tissue region prior to delivering the acoustic energy. Examiner hereby takes Official Notice that it is known in the art to administer blood thinners such as aspirin or heparin to the patient in combination with ultrasound treatment therapy as claimed in the instant application in order to prevent formation or dislodgement of blood clots.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/

Supervisory Patent Examiner, Art Unit

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/Parikha S Mehta/

Examiner, Art Unit 3737